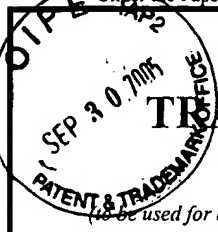


10-03-05

PTO/SB/21 (02/04)

Approved for use through 07/31/2006. OMB 0651-0031
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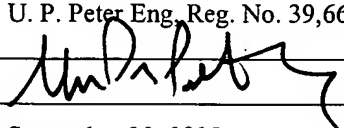
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 TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/645,863	
	Filing Date	08/20/2003	
	First Named Inventor	Jonathan C. Heller	
	Art Unit	1631	
	Examiner Name	Eric S. DeJong	
Total Number of Pages in This Submission	9	Attorney Docket Number	29191-707.201

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): return receipt postcard
Remarks A fee of \$180.00 is authorized to be charged to Deposit Account No. 23-2415 (Docket No. 29191-707.201) for filing of the Supplemental IDS.		

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	U. P. Peter Eng. Reg. No. 39,666, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	September 30, 2005

Express Mail Date: September 30, 2005**Express Mail Label No.: EV518897318US**

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EXPRESS MAIL LABEL NO.: EV 518897318 US

PATENT
Attorney Docket No. 29191-707.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Jonathan C. HELLER, et al.

Serial Number: 10/645,863

Filing Date: August 20, 2003

Title: SYSTEM OF ANALYZING COMPLEX
MIXTURES OF BIOLOGICAL AND OTHER
FLUIDS TO IDENTIFY BIOLOGICAL
STATE INFORMATION

Group Art Unit: 1631

Examiner: Eric S. DeJong

CONFIRMATION NO: 7685

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08A. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

10/04/2005 HLE333 00000115 232415 10645863

01 FC:1806 180.00 DA

☐ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;
-- OR --
- ☐ (3) It is being filed before the mailing date of the first Office Action on the merits;
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;
-- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☒ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.
-- OR --
- ☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.

-- AND/OR --

- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08A are enclosed in accordance with 37 CFR §1.98(a)(2).

-- AND/OR --

- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).
- ☒ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☒ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- WO 2005/024409 was published in German. The English language abstract and the drawings are sufficient to convey the scope of its disclosure.
- Should the Examiner believe that a complete translation of the above mentioned publication is necessary to understand its disclosure, Applicant(s) will endeavor to provide such translation at the Examiner's request.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29191-707.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

By: 

U. P. Peter Eng, Reg. No. 39,666

Dated: September 30, 2005

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

CERTIFICATION

(Attachment to Information Disclosure Statement)

- ☐ 37 C.F.R. §1.97(e)(1). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☒ 37 C.F.R. §1.97(e)(2). **APPLICANT'S UNDERSIGNED ATTORNEY HEREBY CERTIFIES THAT** no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement.

Respectfully submitted,



By:

U. P. Peter Eng
Reg. No. 39,666

Dated: September 30, 2005

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Customer No. 021971

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/645,863
				Filing Date	08/20/2003
				First Named Inventor	Jonathan C. Heller
				Art Unit	1631
Examiner Name	Eric S. DeJong				
Sheet	1	of	4	Attorney Docket Number	29191-707.201

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-5,652,427	07-29-1997	Whitehouse, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 2004/055519 A2	07-01-2004	Hoffmann La Roche (CH), et al.		
		WO 2004/061407 A2	07-22-2004	Caprion Pharmaceuticals Inc (CA), et al.		
		WO 2004/061410 A2	07-22-2004	Ciphergen Biosystems Inc (US), et al.		
		WO 2004/068130 A2	08-12-2004	Mosaïques Diagnostics and Therapeutics AG (DE), et al.		
		WO 2004/102190	11-25-2004	Europroteome AG (DE), et al.		
		WO 2005/011474	02-10-2005	Correologic Systems Inc (US), et al.		
		WO 2005/020125	03-03-2005	Beyond Genomics Inc (US), et al.		
		WO 2005/024409	03-17-2005	Mosaïques Diagnostics and Therapeutics AG (DE), et al.		✓

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/645,863
				Filing Date	08/20/2003
				First Named Inventor	Jonathan C. Heller
				Art Unit	1631
				Examiner Name	Eric S. DeJong
Sheet	2	of	4	Attorney Docket Number	29191-707.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		FUNG, Eric T., et al., "Classification of cancer types by measuring variants of host response proteins using SELDI serum assays," <i>Int. J. Cancer</i> (2005) 115:783-789	
		KAISER, Thorsten et al., "Capillary electrophoresis coupled to mass spectrometer for automated and robust polypeptide determination in body fluids for clinical use". <i>Electrophoresis</i> (2004), 25:2044-2055.	
		KAJITA, Yoshihiro, et al., "Clinical Study on Increased Serum Thyroxine-Binding Globulin in Cancerous State," <i>Endocrinol. Japon</i> (1981) 28 (6): 785-791	
		KOO, Edward D., et al., "Amyloid diseases: Abnormal protein aggregation in neurodegeneration," <i>Proc. Natl. Acad. Sci.</i> (August 1990) Vol. 96: 9989-9990	
		KUNDIN, W.D., et al., "Cancer Serum Index: A useful Nonspecific Test as a Parameter in Multimodality Screening and Assessment of Patients With Cancer of the Prostate," <i>The Prostate</i> (1981) 2:207-217	
		LI, JINONG, et al., "Detection of prostate cancer using serum proteomics pattern in a histologically confirmed population". <i>The Journal of Urology</i> (May 2004), 171:1782-1787.	
		MOBLEY, J.A., et al., "Monitoring The Serological Proteome: The Latest Modality in Prostate Cancer Detection," <i>The Journal of Urology</i> (July 2004) Vol. 172: 331-337	
		ORNSTEIN, David K., et al., "Serum Proteomic Profiling Can Discriminate Prostate Cancer From Benign Prostates in Men With Total Prostate Specific Antigen Levels Between 2.5 And 15.0 NG/ML," <i>The Journal of Urology</i> (October 2004) Vol. 172: 1302-1305	
		PARONI, Rita et al., "Creatinine determination in serum by capillary electrophoresis". <i>Electrophoresis</i> (2004), 25:463-468.	
		REIXACH, Natalia, et al., "Tissue damage in the amyloidoses: Transthyretin monomers and nonnative oligomers are the major cytotoxic species in tissue culture," <i>PNAS</i> (March 2, 2004) Vol. 101 No. 9: 2817-2822	

Examiner signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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				Application Number	10/645,863
				Filing Date	08/20/2003
				First Named Inventor	Jonathan C. Heller
				Art Unit	1631
				Examiner Name	Eric S. DeJong
Sheet	3	of	4	Attorney Docket Number	29191-707.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ROBEY, Edwin L., et al., "Cancer Serum Index And Prostatic Acid Phosphatase For Detection Of Progressive Prostatic Cancer," <i>The Journal of Urology</i> (October 1985) Vol. 134: 787-790	
		ROSTENBERG, Israel, et al., "Gc Globulin and Prealbumin Serum Levels in Patients With Cancer and Benign Inflammatory Diseases and in Asymptomatic Smokers," <i>Journal of the National Cancer Institute</i> (February 1997) Vol. 62 No. 2:299-300	
		SASSI, Alexander P., et al., "An automated, sheathless capillary electrophoresis-mass spectrometry platform for discovery of biomarkers in human serum". <i>Electrophoresis</i> (2005),26:pages unknown.	
		SCHWEIGERT, Florian J., et al., "Transthyretin, a Biomarker for Nutritional Status and Ovarian Cancer," <i>Cancer Research</i> (February 1, 2005) 65 (3):1114	
		THOMPSON, Ian M., et al., "Prevalence of Prostate Cancer among Men with a Prostate-Specific Antigen Level ≤ 4.0 ng per Milliliter," <i>The New England Journal of Medicine</i> (May 27, 2004) Vol. 350 No. 22: 2239-2246	
		VEJDA, Susanne, et al., "Plasma from Cancer Patients Featuring a Characteristic Protein Composition Mediates Protection against Apoptosis," <i>Molecular & Cellular Proteomics</i> (2002):387-393	
		VILLANUEVA, Josep et al., "Serum peptide profiling by magnetic particle-assisted, automated sample processing and MALDI-TOF mass spectrometry". <i>Anal. Chem.</i> (March 15, 2004), 76(6):1560-1570.	
		WARD, A. Milford, et al., "Acute Phase Reactant proteins in Prostatic Cancer," <i>British Journal of Urology</i> (1977), 49: 411-418	
		ZHANG, Zhen, et al., "Three Biomarkers Identified from Serum Proteomic Analysis for the Detection of Early Stage Ovarian Cancer," <i>Cancer Research</i> (August 15, 2004) 64:5882-5890	

Examiner signature		Date Considered	
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known		
				Application Number	10/645,863	
				Filing Date	08/20/2003	
				First Named Inventor	Jonathan C. Heller	
				Art Unit	1631	
				Examiner Name	Eric S. DeJong	
Sheet	4	of	4	Attorney Docket Number		29191-707.201

CO-PENDING/PUBLISHED/ISSUED PATENT MATTERS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		STULTS, et al., U.S. Patent Application No. 11/178,262, entitled "Systems and Methods for Discovery and Analysis of Markers," filed 07-08-2005 (WSGR Reference No. 29191-707.502)	
		HELLER, et al., U.S. Patent Application No. 11/178,245, entitled "Biological Patterns For Diagnosis And Treatment Of Cancer," filed 07-08-2005 (WSGR Reference No. 29191-729.201)	

Examiner signature		Date Considered	
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